

VALIDATION RESULTS FOR METHOD NO. Covance Harrogate 2001-032-D1					
ANALYTE	MDA	MEAN	RELATIVE STD. DEV. (%)	RANGE	SEE (conc)
MATRIX	Human plasma				
DATE	15-Aug-01				
LLOQ	0.4 µmol/L	0.4 µmol/L	Accuracy 107.5%		
			RSD 6.0%		
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) (SEE = S.D./SQRT (# of determinations))					
	1 µmol/L	Low QC			0.012
	4 µmol/L	Med QC			0.034
	8 µmol/L	High QC			0.068
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quadratic, etc.)	Linear				
Slope (mean)	67927				
Intercept (mean)	7935				
Other (mean regression value)	0.98855(1/x weighted)				
RECOVERY (as a %)					
High QC in (matrix)=	8 µmol/L	92.5%	Calculated as a % of the peak area observed for derivatised water standards		
Med QC in (matrix)=	4 µmol/L	94.7%			
Low QC in (matrix)=	1 µmol/L	100.0%			
Results with different sample amounts (results of QC evaluations) intra-assay					
LLOQ QC=	0.4 µmol/L	0.43	6.0%	0.39-0.45	0.013
Low QC=	1 µmol/L	0.94	4.1%	0.90-1.00	0.016
Med QC=	4 µmol/L	3.90	2.2%	3.79-4.05	0.035
High QC=	8 µmol/L	7.55	2.4%	7.34-7.82	0.075
Results with different sample amounts (results of QC evaluations) inter-assay					
LLOQ QC=	n/a	n/a	n/a	n/a	n/a
Low QC=	1 µmol/L	0.95	6.1%	0.84-1.10	0.012
Med QC=	4 µmol/L	3.84	4.3%	3.54-4.15	0.034
High QC=	8 µmol/L	7.50	4.5%	6.85-8.10	0.068
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/12 hrs)		7.7% maximum			
b) Freeze/thaw (+/- % /3 cycles)		3.3% maximum			
c) Processed sample (+/- %/24 hrs)	20 hrs refrigerated plus duration of batch	% maximum			